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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,205	05/15/2006	Ezio Bombardelli	2503-1186	5416

466 7590 03/13/2007

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,205	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	Catheryne Chen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 8* is/are rejected.

7)☒ Claim(s) *1-4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *DEc. 23, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-5, 7-8 are pending. Claims 1-5, 7-8 are examined on the merits. Claims 6 and 9 are canceled.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-5, 7-8) in the reply filed on Jan 26, 2007 is acknowledged. The election of species is referred to Example 1 in the Specification, which are Salix rubra extract, Boswellia serrata extract, Green Tea extract, N-acetyl-glucosamine, Glucuronolactone, Enothera biennis oil. Claims 6 and 9 are canceled.

Claim Objections

Claims 1-4 are objected to because of the following informalities: The word procyanidins is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not known whether the formulation comprises of all of the ingredients or not because there is no "and" between the second to last and last ingredients. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrubasik et al. (Pain Digest, 1998, 8: 231-236), Tameja et al. (US 5629351), Charters et al. (US 6541045), Kemper (http://www.mcp.edu/herbal/default.htm), Lockhoff et al. (US 4710491).

Chrubasik et al. teaches anti-inflammatory drugs of 360 mg, 11% of salicylic alcohol from Salix species (abstract, Clinical Studies). However it does not teach Boswellia serrata, procyanidins from Camellia sinensis, N-acetyl-glucosamine, glucuronolactone.

Tameja et al. teaches gum resin of Boswellia serrata has been used for the treatment of arthritis (column 1, lines 9-11), at 10 g (column 9, line 14), ranging from 1% to 55% by weight (column 11, lines 66-67; column 12, lines 1-5).

Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44).

Kemper teaches proanthocyanidin in green tea is effective for treating inflammation (page 2).

Lockhoff et al. teaches anti-arthritic compound of 15 g of D-glucuronolactone (column 11, line 6).

The references also do not specifically teach combining all of the claimed ingredients together. The references do teach that the ingredients are for treating inflammation (see references above). As discussed in MPEP 2144.06:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, is would be obvious to combine ingredients that have anti-inflammatory activities together because they are taught in the reference to have the same purpose.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1-4,5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrubasik et al. (Pain Digest, 1998, 8: 231-236), Tameja et al. (US 5629351), Charters et al. (US 6541045), Kemper (http://www.mcp.edu/herbal/default.htm), Lockhoff et al. (US 4710491) as applied to claims 1-4 above, and further in view of Chen et al. (US 2002/0032171 A1) and Belch et al. (The American Journal of Clinical Nutrition, 2000, 71: 352S-356s).

See discussion above. However, they do not teach Oenothera biennis oil.

Chen et al. teaches triglyceride of Oenothera biennis oil (evening primrose) to improve delivery of therapeutic agents (paragraphs 0002, 0036 Table 1).

The references also do not specifically teach combining the claimed ingredients together. The reference does teach that the ingredients are all inflammatory mediators (see discussion above and Belch, abstract). As discussed in MPEP 2144.06:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, is would be obvious to combine ingredients with anti-inflammatory activities together because they are taught in the reference to have the same purpose.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hoffman
2-22-07
SUSAN COE HOFFMAN
PRIMARY EXAMINER

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Art Unit 1655